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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,575	02/15/2001	Tim Cantrell	23101.0003U1	1832

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/26/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/784,575	Applicant(s) CANTRELL ET AL.	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-31-03 (courtesy copy filed 6-9-03).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Perry, Goldberg, Robertson & Johnston

DETAILED ACTION

Election/Restrictions

This application contains claims 1-58 and 81-87 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's arguments filed March 31, 2003, paper number 10, have been fully considered but they are not fully persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 59-80 are under consideration in the instant office action.

Claim Rejections - 35 USC § 101

Applicants argue the specification states an "oviposited egg" refers to an avian egg in a shell, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird (pg 7, lines 23-25). Applicants point to Etches of record (1997, Methods Mol. Biol., Vol. 62, pg 433-450) who also refers to "eggs expelled from the shell gland at the time of oviposition" (pg 435, line 3-4) and to eggs extruded from the vagina as being oviposited (pg 436, lines 10-21). Applicants state that an egg extruded from the vagina having a shell and a zygote or an embryo having less than 30,000 cells as claimed is different than a fertilized egg extruded from the vagina that occurs naturally because they have 60,000 cells in the embryo. Applicants' argument is persuasive. While Robertson of record (1997, J. Reprod. Fertility, Vol. 110, pg 205-211;

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pg 206, col. 1 2nd para.) refers to oviposition as a newly ovulated ova, applicants may be their own lexicographer and have clarified which definition to use in the specification.

Therefore, the utility rejection of claims 59-80 has been withdrawn.

Claim Rejections - 35 USC § 112 – new matter

Claims 59-65 and 77-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases “embryo that develops and hatches in the shell” (59, 64, 65), “shell that formed around a female pronucleus that developed into the embryo” (59, 64), “shell that formed around a female pronucleus that developed into the zygote” (65), “fertilizing an ovum by delivery a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg” (77) and “shell that formed around the yolk during shell membrane deposition and calcification” (78-80) are new matter. Applicants have not pointed to support by page and line number and none can be found in the specification as originally filed.

Claim Rejections - 35 USC § 112 - enablement

The rejection of claims 59-80 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention has been withdrawn in view of applicants' arguments.

Claim Rejections - 35 USC § 112 – indefiniteness

The rejections of claims 59-80 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in view of applicants' arguments.

Claims 59-65 and 77 as newly amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While an embryo can develop in a shell and hatch out of a shell, an embryo does not "hatch in a shell" as claimed (59, 64, 65).

While a female gamete and a male gamete may combine to develop into an embryo, a "female pronucleus" does not develop into an embryo. Therefore the phrase "a female pronucleus that developed into the embryo" or "...zygote" does not make sense (59, 64, 65).

Claim 77 does not make sense because the sperm is delivered into the egg, wherein the egg comprises a zygote. Sperm is not delivered to an egg that has a fertilized egg.

Claim Rejections - 35 USC § 102

The rejection of claims 59-80 under 35 U.S.C. 102(b) as being anticipated by Tanaka (1994, J. Reprod. Fert., Vol. 100, pg 447-449) has been withdrawn. Tanaka taught isolating a chicken oocyte after ovulation. The oocyte was fertilized *in vitro* to form a zygote and transferred into the birth canal of a hen. The hen laid an egg comprising an embryo the next day that developed into a chick (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1; pg 448, col. 1, line 4; pg 448, col. 2, first full para., line 9). While Tanaka referred to the ovulated oocyte as an "oviposited egg" as claimed, the specification states "reference to an avian egg in a shell refers to an oviposited egg, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird" (pg 7, lines 23-25). Applicants may be their own lexicographers. Love (Jan. 1994, Bio/Technology, Vol. 12, pg 60-63) taught the first 24 hours of chick development take place in the oviduct, and that by the time egg is laid, the embryo has about 60,000 cells. The fertilized oocyte of Tanaka was not extruded from the vagina until the day after being transferred into the birth canal. Therefore, the egg extruded from the vagina of the bird taught by Tanaka comprised an embryo having about 60,000 cells.

The rejection of claims 59-64, 66-74 and 78-80 has been withdrawn because the claims require an oviposited egg comprising an embryo having fewer than 30,000 cells. The rejection of claims 65 and 75-77 has been withdrawn because the claims require an oviposited egg comprising a zygote, which is one cell.

The rejection of claims 59-80 under 35 U.S.C. 102(b) as being anticipated by Perry (1988, Nature, Vol. 331, pg 70-72) has been withdrawn. Perry taught a fertilized oocyte recovered from the magnum of a killed hen surrounded by a capsule of dense, viscous albumen (pg 71, Fig. 1A caption). The specification states "reference to an avian egg in a shell refers to an oviposited egg, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird" (pg 7, lines 23-25). The rejection has been withdrawn because the fertilized oocyte isolated by Perry was not an egg with a calcium carbonate shell or "oviposited" (extruded from the vagina) as claimed.

Claims 59-80 remain rejected under 35 U.S.C. 102(b) as being anticipated by Johnston (1998, Poultry Science, Vol. 77, pg 142) for reasons of record.

Johnston taught a fertilized oocyte (6 lines from the bottom) made by injecting sperm into oviposited eggs (line 9). A fertilized oocyte is a zygote or embryo (less than 10,000 cells) because it is one cell that proliferated and was capable of hatching (last sentence). The fertilization of an oviposited egg as taught by Johnston inherently requires an opening in the shell because it was fertilized *in vitro*. The shell inherently formed around a female pronucleus and yolk because it formed around an unfertilized ovum. The method used to make the egg of Johnston is identical to the method disclosed in the instant specification.

Applicants argue Johnston did not teach the egg hatched. Applicants' argument is not persuasive. The egg taught by Johnston is capable of hatching which is all that is required in the claims and equivalent to the teachings in the specification, i.e. the

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specification does not teach maintaining the egg until hatch. Applicants other arguments are generic and do not specifically point to limitations not taught by Johnston or point to errors in the rejection.

Claims 66-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Naito (1990, J. Exp. Zoo., Vol. 254, pg 322-326) as supported by Olsen (J. Morph., 1942, Vol. 70, pg 513-533, Ref DC in the IDS filed 9-4-01).

Naito taught isolating a chicken embryo 2.5-2.75 hr after fertilization from the reproductive tract of a chicken. The embryo was transferred into an eggshell with a hole drilled in it and incubated until hatch (pg 323, col. 1, Systems I and II). The embryo is inherently a zygote (one cell) because it is less than 3 hours old (Olsen, pg 523, lines 1-3). The egg is an "oviposited egg" because the egg has "a calcium carbonate shell that has been extruded from the vagina of a bird" as defined in the specification. The size of the opening being less than 4 or 1 cm does not produce an article for use that possesses a new or distinctive form, quality or property. The size of the opening only defines what may enter the shell. There is no change in the name, appearance, or general character of the egg. It remains an egg with an embryo having fewer than 30,000 or 20,000 cells fit only for the same beneficial uses as the egg of Naito.

American Fruit Growers Inc. v. Brogdex Co., 1931 C.D. 711, 404 O.G. 1043, 283 U.S. 1, 8 USPQ 131, 133.

Claim Rejections - 35 USC § 103

Claims 59-80 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (1998, Poultry Science, Vol. 77, pg 142) in view of Goldberg (1992, Ped. Research, Vol. 32, pg 23-26) for reasons of record.

Johnston taught an oviposited avian egg having less than 10,000 cells as claimed (see 102 rejection above). Johnston did not teach making a window less than 5 mm as claimed. However, Goldberg taught making a 1 mm window in avian eggs having embryos to inject various solutions (para. bridging pg 23-24). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain an oviposited avian egg having less than 10,000 cells as taught by Johnston and make a 1 mm window in the egg as taught by Goldberg. One of ordinary skill in the art at the time of the invention would have been motivated to inject sperm into the eggs of Johnston in a 1 mm window to decrease the amount of damage to the eggshell and to maintain the integrity of the eggshell. One of ordinary skill in the art at the time of the invention would have been motivated to use the eggs of Johnston in teratogenic studies to determine if manipulating eggs as taught by Johnston effect teratogenesis.

Applicants argue Johnston taught the egg was removed from its shell. Applicants' argument is not persuasive. Johnston taught oviposited eggs were fertilized not oviposited eggs removed from their shell. Applicants argue Johnston did not teach the egg hatched. Applicants' argument is not persuasive. The egg taught by Johnston is capable of hatching which is all that is required in the claims; the claims are not

directed toward a hatched egg, i.e. an avian. Applicants argue no motivation exists to combine the references; however, the examiner has provided a motivational statement why the references would be combined by one of ordinary skill in the art.

Double Patenting

The rejection of claims 59-80 under double patent with claims of Application No. 09/784803 has been withdrawn in view of the restriction requirement in 09/784803 and in the instant application.

The rejection of claims 59-80 under 35 U.S.C. 101 as claiming the same invention as that of claims of copending Application No. 09/7845803 has been withdrawn because the claims of '803 are drawn to a method of fertilizing an oviposited egg in a shell.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER